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MAY - 6 2008

510(k) SUMMARY

XCHF-B180Y1 Choledochoscope

1. General Information

Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Establishment Registration No: 8010047

Official Correspondent: Laura Storms-Tyler
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway, PO Box 610
Center Valley PA 18034-0610
Phone: (484) 896-5688
Facsimile: (484) 896-7128
Email: Laura.storms-tyler@olympus.com
Establishment Registration No: 2429304

Manufacturer:

Light source/Video system center: SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148

Choledochoscope: Aizu Olympus Co., Ltd.
500 Aza-Muranishi, Ooaza-Niidera, Monden-machi,
Aizuwakamatsu-shi, Fukushima, Japan 965-8520
Establishment Registration No.: 9610595

Date Prepared: April 30, 2008

2. Device Identification

Device Name: XCHF-B180Y1 Choledochoscope
Common Name: Choledochoscope
Class: II
Regulation Number/Name: 876.1500 Endoscope and accessories
Product Code: FBN/ NWB
Classification Panel: Choledochoscope And Accessories, Flexible/ Rigid
Endoscope, accessories, narrow band spectrum

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3. Legally Marketed Device to which Substantial Equivalence is Claimed

The following table shows the subject device and the predicate device to which we claim substantial equivalence.

**Table 13-1:
Primary Component & Predicate Device**

Subject Device (part of this submission)	Predicate Device	PD's 510(k) No.
XCHF-B180Y1Choledochoscope	CHOLEDOCHOSCOPE XCHF-BP160F	K051886

4. Device Description

The XCHF-B180Y1, is a flexible video endoscope used for endoscopy and endoscopic surgery within the biliary tract and pancreatic duct. The XCHF-B180Y1 is basically identical to the predicate device, Olympus XCHF-BP Type 160F Choledochoscope, hereinafter referred to as XCHF-BP160F in intended use, specifications, performance. The optical system of the XCHF-B180Y1 is a charge coupled device (CCD) based system, allowing endoscopic image display on a video monitor.

The new endoscope is basically identical to each predicate device shown in Table 13-1 in intended use, and similar in specifications, performance and materials.

5. Indications for Use

XCHF-B180Y1 Choledochoscope

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the biliary tract and pancreatic duct in conjunction with the EVIS DUODENOSCOPE with an instrument channel with a minimum diameter of $\phi 4.2$ mm.

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6. Comparison of Technological Characteristics

The XCHF-B180Y1 is similar to the predicate device XCHF-BP160F in specifications except for the material and optical system. Comparison between the subject and predicate devices is shown below.

Table 13-2. Comparison of Specifications

Specifications	Subject Device XCHF-B180Y1	Predicate Device XCHF-BP160F (K051800)
Field of View	90°	90°
Direction of View	Forward Viewing 0°	Forward Viewing 0°
Depth of Field	2~50mm	2~50mm
Type of CCD Chip	Color CCD	Color CCD
Outer Diameter of Distal End	φ 3.4mm	φ 2.8mm
Outer Diameter of Insertion Tube	φ 3.8mm	φ 3.7mm
Angulation	UP : 70 DOWN : 70	UP : 70 DOWN : 70
Working Length	2000mm	2000mm
Inner Diameter of Instrument Channel	φ 1.2mm	φ 1.2mm

6. Conclusion

When compared to the predicate device, the XCHF-B180Y1 does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Laura Storms-Tyler
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K080586

Trade/Device Name: CHOLEDOCHOSCOPE XCHF-B180Y1
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBN
Dated: February 28, 2008
Received: March 5, 2008

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

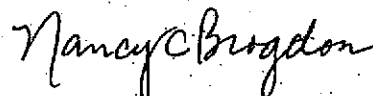
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080586

Device Name: CHOLEDOCHOSCOPE XCHF-B180Y1

Indications For Use:

CHOLEDOCHOSCOPE XCHF-B180Y1

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the biliary tract and pancreatic duct in conjunction with the EVIS Duodenoscopes with an instrument channel with a minimum diameter of $\phi 4.2\text{mm}$.

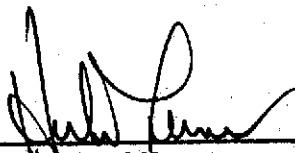
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080586

Page 1 of 1